

Remarks

Claims 1, 6, 7, 9, 10, 14, 15, 18, 19, and 21 stand rejected under 35 U.S.C. 102(c) as being unpatentable over Berney (US 5,777,303) in view of Bowman (US 5,135,313). Claim 2 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, and further in view of disclosure of RD 421048 A. Claims 3, 4, 11, and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, and further in view of Stevens et al. (EP 1,004,359 A2). Claims 5 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman and Stevens et al. and further in view of Leuenberger (US 5,314,421). Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A and Leuenberger. Claims 16, 20 and 39-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman and further in view of Fukuzaki (US 5,948,103). Claims 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki, and Coli et al. (US 6,018,713).

For the most part, insertions previously made to the claims to the effect that the tags are “tamper indicating” have been deleted. Thus, no estoppel should arise in connection with that now-deleted recitation.

The applicant’s invention provides a diagnostic specimen system comprising a biomedical specimen collection vessel and a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information. The electronic memory tag may include a radiofrequency transponder. The diagnostic specimen system may include data stored on the electronic memory tag including an identification code for the container, the identity of the container and product information about the container, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel. The system may also include a label imprinted with a container-identifying bar code. A tamper-indicating feature may indicate if someone tries to remove the label or adulterate the contents of the container.

The invention further provides a method of managing the gathering of diagnostic specimens from multiple specimen collection sites and the delivery of the collected specimens

to a testing laboratory. Claims 1-15, 18-19, and 21 have hereby been amended in accordance with the application's original disclosure to emphasize this aspect of the applicant's invention.

The applicant's invention, in this aspect, uses a diagnostic specimen system including a population of specimen collection vessels, each having a wireless electronic memory tag attached to the vessel. The population includes at least one member at a vessel distribution facility, at least one member at a specimen collection facility, and at least one member at a specimen testing laboratory. The system enables collecting identity and test data for specimens and specimen donors at a collection site, entering the collected data into a computer database, and transmitting the collected data from the collection site computer database to a computer at a testing laboratory by an internet connection. This system includes many advantages over the prior art. For example, users can realize optimal specimen and vessel delivery and pick-up schedules to and from the specimen collection and testing facilities. Also, the system enables automated specimen analysis at a laboratory facility, improving security of the specimens. Accordingly, the Examiner is respectfully requested to reconsider the rejection of claims 1-15, 18-19, and 21 in view of the amendment hereby presented.

With respect to the examiner's obviousness rejection of claims 16, 17, 20 and 38, it is well settled that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. ACS Hospital Systems, Inc. v. Montefiori Hospital, 732 F.2d. 1572, 1577, 221 U.S.P.Q. 929, 939 (CAFC 1984) (emphasis added). Here, the examiner has merely interjected an opinion that "the information contained in Berney-Bowman's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case." Office Action mailed 10/3/2003 at page 8.

Fukuzaki discusses adding electronic security to documents that are electronically transmitted. Only hindsight, guided by the applicant's disclosure suggests carrying such an security or identification feature to a collection specimen container. It appears, respectfully, that the examiner has impermissibly used the applicant's invention as a blueprint to search the

prior art for elements comprising the applicant's invention, and filled gaps in the references by interjecting personal knowledge, unsupported opinion, speculation, or mere conjecture. Broad conclusory statements are not evidence of obviousness. In the case of In re Lee, 61 USPQ2d 1431, (Fed. Cir. 2002) the Court indicated that the findings under 35 U.S.C. 103 must be based on evidence and reasoned findings that one of ordinary skill in the art would have been motivated to combine the references. The Court further indicated that the findings and the grounds thereof must be clearly indicated on the record. The Office Action does not reveal any evidence in support of the conclusion of obviousness. The showing must be clear and particular. *See In re Dembiczak* 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). While it is acknowledged that certain elements of the cited references can be combined, the mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. (Emphasis added). In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 1990). In re Mills, 916 F.2d 680 16 USPQ2d 1430 (Fed. Cir. 1990). MPEP §2143.01. If the examiner wishes to rely on the examiner's personal knowledge to support a rejection, the examiner should submit an affidavit into the record in accordance with MPEP §2144.03.

Therefore, a prima facie case of obviousness has not been established with respect to claims 16, 17, 20, and 38. Claims 16, 17, and 20 have been rewritten as previously presented, including any independent claims from which they depend (absent the now-deleted references to tamper-evident features), and numbered 42, 43, and 44, respectively.

With this amendment, claim 39 has been cancelled. New claims 40-41 have been added for examination. Claim 41 depends from claim 1 and includes an electronic database for use with the diagnostic specimen system of claim 1. Claim 42 depends from claim 41 and includes an electronic network for use with the diagnostic specimen system of claim 42. Examination of the new claims is respectfully requested.

Enclosed for the examiner's consideration are two newly-cited references and a form PTO-1449 to aid the examiner in making his consideration of the references of record.

The Applicant submits that by this amendment he has placed the case in condition for immediate allowance and such action is respectfully requested. However, if any issue remains unresolved, Applicant's attorney would welcome the opportunity for a telephone interview to expedite allowance and issue.

Respectfully submitted,



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